

REMARKS

This Amendment is being filed in response to the Office Action mailed from the U.S. Patent and Trademark Office (USPTO) on November 21, 2003, in which claims 1, 5, 17, and 26 were objected to and claims 1-31 were rejected. With this Amendment, the Abstract is amended and claims 1, 5, 9, 17 and 26 are amended. As such, Applicants respectfully request reconsideration and allowance of pending claims 1-31.

The Office Action rejected claims 1-21 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,692,139 to Stiles ("the Stiles '139 patent"). The Office Action also rejected claims 1-4, 8-12 and 16 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,782,861 to Cragg et al. ("the Cragg et al. '861 patent"). The Office Action also rejected claims 17-23, 25-29 and 31 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,508,782 to Evans et al. ("the Evans et al. '782 patent"). The Office Action rejected claims 5-7, 13-15, 24 and 30 under 35 U.S.C. 103(a) as obvious in light of various combinations of Stiles '139 patent, Cragg et al. '861 patent and Evans et al. '782 patent.

Applicants hereby gratefully acknowledge the telephone conferences with Examiner Bradford C. Pantuck on February 3, 2004 in which Applicants' attorney, David J. Dykeman, and Examiner Pantuck discussed the Office Action mailed on November 21, 2003 and the cited prior art of the Stiles '139 patent, the Evans et al. '782 patent and the Cragg et al. '861 patent.

Applicants also acknowledge the brief telephone conference with Examiner Pantuck on November 25, 2003 to discuss the information disclosure statement filed on February 22, 2002. The Office Action stated that the information disclosure statement filed February 22, 2002 fails to comply with 37 CFR 1.98(a)(1) and the information disclosure statement filed February 22, 2002 has been placed in the application file but the information referred to therein has not been considered. As discussed with Examiner Pantuck on November 25, 2003 and February 3, 2004, a form 1449 was filed with the original application on February 22, 2002 and acknowledged as received by the USPTO. Filed herewith is a copy of the February 22, 2002 Form 1449 listing 19 patents and a copy of the postcard showing the February 22, 2002 Form 1449 was mailed on February 22, 2002 and received by the USPTO. As discussed with Examiner Pantuck on

November 25, 2003 and February 3, 2004, Applicants request consideration of the references and initialization of the Form 1449 filed February 22, 2002.

The Office Action objected to the Abstract and claims 1, 5, 17 and 26 for informalities. The Office Action also rejected claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With this Amendment, the Abstract and claims 5, 17 and 26 have been amended to replace the term “a debris” with the term “debris.” With this Amendment, claim 1 has been amended to recite that the anchoring mechanism is adapted to engage an inner surface at a puncture site of the vascular access device. Thus, the objections to the informalities are overcome.

Anticipation Rejections Under 35 U.S.C. 102(b)

The Office Action rejected claims 1-21 under 35 U.S.C. 102(b) as being anticipated by the Stiles ‘139 patent. The Office Action also rejected claims 1-4, 8-12 and 16 under 35 U.S.C. 102(b) as being anticipated by the Cragg et al. ‘861 patent. The Office Action also rejected claims 17-23, 25-29 and 31 under 35 U.S.C. 102(b) as being anticipated by the Evans et al. ‘782 patent.

To anticipate a claim, the reference must teach every element of the claim. M.P.E.P. 2131. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987); M.P.E.P. 2131. “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989); M.P.E.P. 2131.

The Office Action rejected claims 1-21 under 35 U.S.C. 102(b) as being anticipated by the Stiles ‘139 patent. The Office Action states on pages 4-6 that Stiles discloses a vascular introducer for insertion into a blood vessel:

Regarding Claims 1, 2, and 9-12 Stiles discloses a vascular introducer for insertion into a blood vessel. His introducer has an elongated shaft (1) and an anchoring mechanism (5). The anchoring mechanism (5) has a retracted position [see Fig. 1] and an extended position [see Fig. 3] in which the anchor is able to engage the inner surface of the artery [Column 3, lines 54-57].

The Office Action rejected claims 17-23, 25-29 and 31 under 35 U.S.C. 102(b) as being anticipated by the Evans et al. '782 patent. The Office Action states on pages 8-9:

Regarding Claims 17-20 and 27, Evans discloses a method of clearing debris from a blood vessel, including all of the mentioned steps. Evans discloses placing the vascular introducer into the vascular access device [Column 1, lines 21-25], and ablating debris using the ultrasonic probe [Column 5, lines 34-41]. The introducer need not be removed from the artery during ablation because a vacuum (102) sucks the debris out through the tube (10) [Column 8, lines 19-28]. The debris can be a blockage/occlusion [Column 3, lines 24-28].

Regarding Claims 22 and 28, Evans discloses a method of employing an anchor (120) that maintains contact between the vascular introducer and the blood vessel (55) to prevent removal or detachment of the introducer from the blood vessel [see Fig. 18].

The Office Action rejected claims 1-4, 8-12 and 16 under 35 U.S.C. 102(b) as being anticipated by the Cragg et al. '861 patent. The Office Action states on pages 6-8 that the Cragg et al. '861 patent discloses a vascular introducer for insertion into a blood vessel:

Regarding Claims 1, 2, and 9-12 Cragg discloses a vascular introducer for insertion into a blood vessel [Column 4, line 62 to Column 5, line 2]. His introducer has an elongated shaft (18) and an anchoring mechanism (42). The anchoring mechanism (42) has a retracted position [see Fig. 1] and an extended position [see Fig. 11] in which the anchor engages the inner surface of the artery [Column 7, lines 55-59].

Regarding Claim 3, Cragg discloses a vascular introducer with an anchoring mechanism (42) that maintains contact between the vascular introducer and the blood vessel to prevent removal or detachment [Column 7, lines 55-67]. Cragg grips the vessel tightly, having its hook shape end pierce the vessel. While the anchoring mechanism (42) is still attached to the shaft (38), the anchoring mechanism (42) will maintain contact between the vascular introducer and the blood vessel to prevent removal or detachment.

With this Amendment, Applicants have amended claims 1, 9 and 17 to claim a vascular introducer comprising an anchoring mechanism that resides within the elongated shaft when the

anchoring mechanism is in a retracted position and extends beyond the proximal insertion end of the elongated shaft and **is adapted to engage an inner surface at a puncture site** of the vascular access device when the anchoring mechanism is in an extended position, wherein the **vascular introducer is atraumatic to an area surrounding the puncture site**. None of the Stiles '139 patent, the Cragg et al. '861 patent and the Evans et al. '782 patent disclose or suggest a vascular introducer comprising an anchoring mechanism that **is adapted to engage an inner surface at a puncture site** of the vascular access device when the anchoring mechanism is in an extended position, wherein the **vascular introducer is atraumatic to an area surrounding the puncture site**. The Stiles '139 patent and the Evans et al. '782 patent disclose a device that does not engage an inner surface at a puncture site of the vascular access device. The Cragg et al. '861 patent discloses a device that is not atraumatic to an area surrounding a puncture site of the vascular access device.

Argument Regarding Stiles '139 Patent

The Stiles '139 patent discloses a device comprising a catheter for **"insertion into a biological duct via a single incision remote from the vicinity of the obstruction"** and moved into position within the duct. The Stiles device comprises a delivery sleeve having an aspiration tube with a rubber shield on a remote end of the aspiration tube. The Stiles delivery sleeve is inserted into the biological duct and fed through the artery to a position within the biological duct in close proximity to the obstruction. The Stiles rubber shield is deployed remote from the single incision at the site of the obstruction and serves to direct the movement of the fragments of the obstruction within the aspiration tube. The Stiles device is shown in FIGS. 1 and 3 and is described as follows:

According to the present invention, a device is provided for integrating the functions of aspiration, irrigation and ultrasound application within a single catheter, for insertion into a biological duct via a single incision **remote from the vicinity of the obstruction** and moved into position within the duct. (Stiles '139 patent; Col. 2, Lines 28-33) (Emphasis Added).

In order to emulsify and fragment an obstruction such as a blood clot blocking the coronary artery or other artery chambers of the heart, the delivery sleeve 1 is preferably inserted into an appropriate leg artery according to well known surgical techniques, and is **fed through the artery to a position within the coronary**

artery or artery chamber in close proximity to the obstruction. (Stiles '139 patent; Col. 4, Lines 18-25) (Emphasis Added).

Mounted on a **remote end** of aspiration tube 3 is a **folded soft springy rubber shield 5.** (Stiles '139 patent; Col. 3, Lines 38-39) (Emphasis Added).

The shield 5 opens and closes between the deployed and retracted positions with an **action similar to that of opening and closing an umbrella.** (Stiles '139 patent; Col. 3, Lines 54-57) (Emphasis Added).

A catheter as defined in claim 1, further including a collapsible shield connected to said first end of the aspiration tube, said shield being movable between a collapsed position within said delivery tube and a deployed position externally of said delivery tube in response to said aspiration tube being moved between said retracted and extended positions respectively, whereby **in said deployed position the shield directs removal of said fragmented matter from said vicinity** into the aspiration tube. (Stiles '139 patent; Col. 6, Lines 14-23) (Emphasis Added).

The Stiles shield does not serve as an anchoring mechanism and does not engage an inner surface at a puncture site of the vascular access device to secure the vascular introducer. The Stiles '139 patent discloses a device that is inserted into a "biological duct via a single incision remote from the vicinity of the obstruction." The Stiles shield is deployed remote from the single incision at the site of the obstruction and does not engage the inner surface at the puncture site of the biological duct. Therefore, Stiles does not disclose a vascular introducer comprising an anchoring mechanism that **is adapted to engage an inner surface at a puncture site** of the vascular access device when the anchoring mechanism is in an extended position, wherein the **vascular introducer is atraumatic to an area surrounding the puncture site.** Thus, the Stiles '139 patent does not anticipate or suggest the Applicants' claimed invention.

Argument Regarding Evans et al. '782 Patent

The Evans et al. '782 patent device comprises a deployable and expandable filter trap at the distal end of the Evans et al. device that is deployed and expanded within the blood vessel and seals against the vessel wall. The Evans et al. filter traps particulate matter that would otherwise gather downstream. The Evans et al. filter trap is shown in FIGS. 17-20 and described in at least the following passages from the Evans et al. '782 specification:

With respect to FIGS. 17 through 20, there is shown an alternate embodiment of the motion catheter device 10 having a **coaxially filter trap 120**. As similarly shown with respect to the '273 and '236 patents described above, the filter trap 120 is deployable and expandable as shown in FIGS. 17 through 20.

In FIG. 17 the filter trap is in its initial stage of deployment. In FIG. 18 the filter trap has been fully expanded. Additionally, in FIG. 18 there is shown the filter trap 120 used in combination with the occluding mechanism 116. Using a combination of these devices provides the invention with the ability to trap particulate matter 106, whether it flowed against or with the arrows 108. It will be readily appreciated that **any particulate matter traveling in the direction opposite of the arrows would be trapped within the filter trap 120**. The filter trap 120 is made of polymeric mesh and can be expanded to a variety of shapes and sizes. The device 10 (not shown) includes activation mechanism (not shown) which can readily expand or contract the filter trap 120. (Evans et al. '782 patent; Col. 10, Lines 38-57) (Emphasis Added).

Additionally, polymeric shapes such as a frusto-conical shape filter trap alternative embodiment generally indicated by the numeral 122, may alternatively be employed. The filter trap 122, shown in cross section FIG. 19, includes an outer member 124 and an inner member 126. Both members are connected to a shaft 128. **Upon activation both inner and outer members, 124 and 126 respectively, are deployed or expanded within the blood vessel**. Upon deactivation, both members are contracted and fit snugly along shaft 128. The dual filter has the purpose of (1) **sealing against the vessel wall**, (2) capturing large and small particles and the prevention of dissemination of such fragments, (3) the centering of the catheter during motion, (4) capturing and holding particulate matter for dissolution, and (5) capturing of particulate matter allowing blood or smaller particles to flow through, whereby, at the end of the procedure, the filter trap is un-deployed and particulate matter is removed. (Evans et al. '782 patent; Col. 11, Lines 13-30) (Emphasis Added).

The catheter has an inflatable or **expandable member near the distal tip** which, when inflated or expanded, prevents the passage of dislodged thrombus around the catheter. (Evans et al. '782 patent; Abstract) (Emphasis Added).

The Evans et al. filter trap does not engage an inner surface at a puncture site of the blood vessel. The Evans et al. filter trap seals against the vessel wall along an inner diameter of the vessel away from the puncture site. Therefore, Evans et al. does not disclose a vascular introducer comprising an anchoring mechanism that **is adapted to engage an inner surface at a puncture site** of the vascular access device when the anchoring mechanism is in an extended position, wherein the **vascular introducer is atraumatic to an area surrounding the puncture**

site. Thus, the Evans et al. '782 patent does not anticipate or suggest the Applicants' claimed invention.

Argument Regarding Cragg et al. '861 Patent

The Cragg et al. '861 patent device is a hemostasis device comprising a shaft coaxially received within a hollow tube, and having a distal end formed with an opposed pair of resilient grasping prongs. The purpose of the Cragg et al. hemostasis device is to use prongs to "grasp and gather tissue adjacent to the puncture site to obstruct bleeding." The Cragg et al. **prongs terminate in an inwardly turned hook or barb that are used to grab the tissue and inhibit the flow of blood** adjacent the puncture site. The Cragg et al. prongs grab and gather the tissue to **create an obstruction to the flow of blood**. Thus, the Cragg et al. prongs cause trauma to the tissue at the puncture site. The Cragg et al. prongs are shown in FIGS. 3-8 and described at least in the following passages from the Cragg et al. '861 specification:

As shown in FIGS. 1 and 8, each of the **prongs 42 terminates in an inwardly-turned hook or barb 68**. FIG. 10 illustrates a variant distal end portion 40', having four resilient prongs 42', each of which terminates in an outwardly-turned barb 68'. (Cragg et al. '861 patent; Col. 6, Lines 10-15) (Emphasis Added).

As the prongs 42 close toward each other, the barbs 68 at the ends of the **prongs 42 grasp the surrounding tissue and/or the vessel wall tissue**, and gather it together adjacent the puncture site 14, **thereby creating an obstruction to the flow of blood from the site 14**, as shown in FIGS. 5 and 6. It may be advantageous, just prior to or simultaneously with this shaft actuation step, to provide a slight downward pressure (i.e., in the distal direction) on the entire assembly (the device 10 and the trocar 12) to assure a better grasp of tissue by the prongs 42. (Cragg et al. '861 patent; Col. 7, Lines 27-36) (Emphasis Added).

As in the first embodiment, the **closing of the prongs results 142 in tissue** adjacent the puncture site 14 being grasped and gathered together, thereby **stemming the bleeding**. (Cragg et al. '861 patent; Col. 8, Lines 62-65) (Emphasis Added).

Cragg et al. does not disclose a vascular introducer that is atraumatic to an area surrounding the puncture site. Oppositely, the Cragg et al. prongs grasp and gather the tissue adjacent the puncture site and gather the tissue together to stem the bleeding. The Cragg et al. '861 patent teaches a device to close a puncture site which teaches away from Applicants'

claimed invention which is a vascular introducer anchored to the puncture site to allow insertion of an ultrasonic probe through the vascular introducer into a vascular access device. Thus, Cragg et al. does not anticipate or suggest the Applicants' claimed invention. As such, Applicants respectfully request reconsideration and allowance of pending claims 1-31.

Applicants' amended independent claims 1, 5, 17 and 26 recite a vascular introducer comprising an anchoring mechanism that resides within the elongated shaft when the anchoring mechanism is in a retracted position and extends beyond the proximal insertion end of the elongated shaft and is adapted to engage an inner surface at a puncture site of the vascular access device when the anchoring mechanism is in an extended position, wherein the vascular introducer is atraumatic to an area surrounding the puncture site. Support for these Amendments can be found in at least FIG. 1 and FIG. 4 and the following passages from Applicants' specification:

In the extended position shown in FIG. 1 and FIG. 4, the anchoring mechanism 70 extends beyond the proximal insertion end 44 of the elongated shaft 40 and engages an inner surface 22 of the vascular access device 20, **maintaining contact between the vascular introducer 10 and the vascular access device 20.** (Applicants' Specification; P. 12, Para. 2) (Emphasis Added).

In a preferred embodiment of the present invention, the placement of the vascular introducer 10 can be achieved by **an apical puncture** of the vascular access device 20. (Applicants' Specification; P. 23, Para. 2) (Emphasis Added).

The outer shape of **the vascular introducer 10 is designed to be atraumatic** and allows easy placement of the vascular introducer 10 within the vascular access device 20. The anchoring mechanism 70 effectively holds the vascular introducer 10 in place once the vascular introducer 10 is positioned within the vascular access device 20. An important feature of the vascular introducer 10 is that lateral or rocking motion of the vascular introducer 10 does not cause removal of the vascular introducer 10 from the vascular access device 20 because the anchoring mechanism 70 effectively holds the vascular introducer 10 in place and maintains contact with the inner surface 22 of the vascular access device 20 during use. (Applicants' Specification; P. 22, Para. 1) (Emphasis Added).

The anchoring mechanism 70 of the vascular introducer 10 **prevents removal or detachment of the vascular introducer 10 from the vascular access device 20.** (Applicants' Specification; P. 13, Para. 2) (Emphasis Added).

As best shown in FIG. 1, in the extended position, the anchor 72 extends beyond the proximal insertion end 44 of the elongated shaft 40 and the anchor 72 rotates to engage the inner surface 22 of the vascular access device 20, **maintaining contact between the vascular introducer 10 and the vascular access device 20.** (Applicants' Specification; P. 15, Before First Paragraph) (Emphasis Added).

The apparatus and method for using the vascular introducer 10 with the ultrasonic probe 30 of the present invention discloses an inexpensive, easy to use, **low profile vascular introducer 10** that can clear blockages, occlusions or stenosis of the vascular access device 20 when used in conjunction with an ultrasonic probe 30. (Applicants' Specification; P. 24, Last Paragraph) (Emphasis Added).

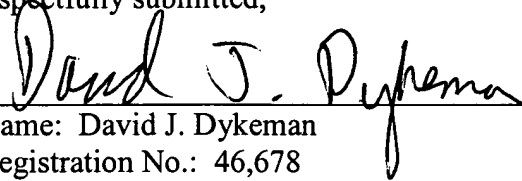
Applicants have amended claims 1, 9, 17 and 26 to claim a vascular introducer comprising an anchoring mechanism that resides within the elongated shaft when the anchoring mechanism is in a retracted position and extends beyond the proximal insertion end of the elongated shaft and is adapted to engage an inner surface at a puncture site of the vascular access device when the anchoring mechanism is in an extended position, wherein the vascular introducer is atraumatic to an area surrounding the puncture site. As such, Applicants respectfully request reconsideration and allowance of pending claims 1-31.

With this Amendment, Applicants have made an earnest effort to respond to all issues raised in the Office Action of November 21, 2003, and to place all claims presented in condition for allowance. No Amendment made was for the purpose of narrowing the scope of any claim, unless Applicants have argued herein that such amendment was made to distinguish over a particular reference or combination of references.

Applicants submit that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicants' attorney would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

Date: February 13, 2004

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "David J. Dykeman", is written over a horizontal line.

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